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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,389

Applicant(s)

CAPUTO ET AL.

Examiner

MONZER R CHORBAJI

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1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-26, 29-43 and 47 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 27, 28 and 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/9/01, 1/6/03, 1/13/03, 6/30/03, 2/13/04, 12/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This general action is in response to the application filing date of 07/09/2001

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, numbered line 16; applicant recites the phrase "means for suddenly commencing" without specifying what is it that is commencing. Is "commencing" refereeing to flowing the sterilant? Explanation is needed to understand the meaning of claim 16. The same applies to claim 29. For now, the meaning of "commencing" is to be interpreted as "commencing the flow of the sterilant gas" in considering claims 16 and 29.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16, 22, 25-26, 29-31, 33-35, 41-43 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Martens et al (U.S.P.N. 5,482,684).

With respect to claims 16 and 30, the Martens reference discloses an apparatus for testing sterilization processes including the following: a gaseous sterilant includes hydrogen peroxide vapor (col.6, lines 12-13), a chamber (figure 1, 14) with an indicator disposed within (abstract, lines 4-5) for contacting with the flowing sterilant (col.7, lines 62-66), means for suddenly commence flowing the sterilant (col.7, line 12-13 such that suddenly is equivalent to the onset of entry of the sterilant through the inlet 28 into the chamber. Also in col.7, lines 26-35 the Martens reference teaches that sterilization conditions must be established over a very short period of time), continuing the contact with the indicator such that the concentration and the flow of hydrogen peroxide in the sterilant during the contact time is maintained constant (col.7, lines 20-21 and lines 54-58), means for suddenly halting the flow of the gaseous sterilant (suddenly is equivalent to stopping the flow of the sterilant at the end of the cycle, for example, in table I, the indicators were exposed to 2 minutes or 120 seconds) with the indicator after the desired contact time have passed (Table I, second test is for 2 minutes or 120 seconds), a chamber with articles placed within to be contacted with the flowing sterilant (col.7, lines 62-66), contacting the articles with the gaseous sterilant that includes hydrogen peroxide such that the concentration and the flow of hydrogen peroxide in the sterilant during the contact time is maintained constant (col.7, lines 20-21 and lines 54-58).

With respect to claims 22, 25-26, 29, 31, 33-35, 41-43 and 47, the Martens reference teaches the following: means for monitoring the hydrogen peroxide vapor (figure 1, 26), maintaining indicator or article in a predefined volume in the chamber

(gas flowing in chamber 14 in figure 1 is contacting the indicator placed on support 44 such that the indicator is stationed in the imaginary volume), means to flow all of the sterilant gas into the chamber through the predefined volume (the predefined imaginary volume is the volume defined between distributors 34 and 36 in figure 1), a method of testing indicators or sterilization processes by placing the indicator or article in the chamber (col.1, lines 5-8) and suddenly flowing the sterilant (col.7, line 12-13 such that suddenly is equivalent to the onset of entry of the sterilant through the inlet 28 into the chamber. Also in col.7, lines 26-35 the Martens reference teaches that sterilization conditions must be established over a very short period of time) and continuing the contact between the gaseous sterilant and the indicator or article under constant concentration and flowing conditions (col.7, lines 20-21 and lines 54-58), suddenly halting the contact between the sterilant and the indicator after the contact time have elapsed (suddenly is equivalent to stopping the flow of the sterilant at the end of the cycle, for example, in table I, the indicators were exposed to 2 minutes or 120 seconds), means for suddenly commencing (suddenly is equivalent to onset of entry of the sterilant through the inlet 28 into the chamber 14) and then continuing the flow of the sterilant in the chamber (col.7, lines 20-21 and lines 54-58) and means for suddenly halting the flow of the gaseous sterilant includes means for rapidly removing the articles from the chamber (col.8, lines 11-14 such that the door is inherently capable of being rapidly opened and rapidly closed).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 9-12, 15, 23-24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) in view of Menden (U.S.P.N. 6,594,017).

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The teachings of the Martens reference have previously been set forth with regard to claims 16, 22, 25-26, 29-31, 33-35, 41-43 and 47; however with respect to claim 1, the Martens reference fails to teach means for rapidly placing the indicator in the chamber while the flow of the gaseous sterilant is continuous. The Menden reference, which is in the art of sensing the flow within vessels, teaches moving in and out sensor means while the flow of gas is continuous (col.1, lines 61-67 and figures 1-2, 2). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor that moves in and out of the chamber while the gas flow is continuous for the sensor support means as taught by the Menden so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it.

With respect to claims 9-12 and 24, the Martens reference teaches the following: maintaining indicator or article in a predefined volume in the chamber (gas flowing in chamber 14 in figure 1 is contacting the indicator placed on support 44 such that the indicator is stationed in the imaginary volume), means to flow all of the sterilant gas into the chamber through the predefined volume (the predefined imaginary volume is the volume defined between distributors 34 and 36 in figure 1), means for monitoring the concentration of the gaseous sterilant (figure 1, 26), means for maintaining the contact of the gaseous sterilant with the indicator at a desired temperature (col.9, lines 59-60) and means for rapidly removing the indicator or article from the chamber after the desired contact time has elapsed (col.8, lines 11-14 such that the door is intrinsically

capable of being rapidly opened resulting in removing the support 44 with the indicator placed on top from the chamber).

With respect to claims 15, 23 and 32, the Martens reference fails to teach placing and removing the indicator or the article while the gas flow is continuous; however, the Menden reference, which is in the art of sensing the flow within vessels, teaches moving in and out sensor means while the flow of gas is continuous (col.1, lines 61-67 and figures 1-2, 2). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor that moves in and out of the chamber while the gas flow is continuous for the sensor support means as taught by the Menden reference so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) as applied to claim 1 in view of Menden (U.S.P.N. 6,594,017) and further in view of Richard et al (U.S.P.N. 6,432,357).

With respect to claim 2, both the Martens reference and Menden reference teach fail to teach pretreating the indicator before contact with the sterilant gas; however, the Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an

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indicator pretreatment humidifying step prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16).

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) as applied to claim 1 in view of Menden (U.S.P.N. 6,594,017) and further in view of Whitbourne et al (U.S.P.N. 3,992,154).

With respect to claim 3, both the Martens reference and Menden reference teach fail to teach post-treating the indicator after they have been removed from the chamber; however, the Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating, col.2, lines 61-64). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment aerating step after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64).

11. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) as applied to claim 1 in view of Menden (U.S.P.N. 6,594,017) and further in view of Richard et al (U.S.P.N. 6,432,357) and Whitbourne et al (U.S.P.N. 3,992,154).

With respect to claims 4-5, both the Martens reference and the Menden reference fail to teach pre-treat or post-treat the indicators with the same members. The Richard reference, which is in the art of vapor sterilization, teaches placing the indicator

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with the articles in a chamber and then humidifying (pretreating means) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44). The humidifying means is part of the chamber sterilization members. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator pretreatment means prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16).

With respect to claims 4-5, the Richard reference fails to teach post-treating indicators. The Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating means, col.2, lines 61-64). The aerating means is part of the chamber sterilization members. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment means after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64).

With respect to claims 6-7, the Martens reference, the Richard reference and the Whitbourne reference all fail to teach the concept of using antechamber that includes pre-treatment and post-treatment by having a movable chamber that moves back and forth between the chamber and the antechamber. The Menden reference discloses antechamber (figure 2, 5) and a movable member (figure 2, 3) and means for moving

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the movable member (figure 2, 10) back and forth between the chamber and the antechamber (figures 1-2, 5, 1 and 3). So, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor member that moves back and forth between the chamber and the antechamber for the sensor support means as taught by the Menden reference so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it.

With respect to claim 8, the Martens reference support means (figure 1, 44) when connected to door (figure 1, 48) as taught in column 8, lines 13-14 is intrinsically capable of rapidly placing and rapidly removing the indicator in the chamber (figure 1, 14).

12. Claims 17 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) in view of Richard et al (U.S.P.N. 6,432,357).

With respect to claims 17 and 36, the Martens reference fails to teach pretreating the indicator before contact with the sterilant gas; however, the Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator pretreatment humidifying step prior to admission of the gaseous sterilant as taught by the Richard

reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16).

13. Claims 18 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) in view of Whitbourne et al (U.S.P.N. 3,992,154).

With respect to claims 18 and 37, the Martens reference fails to teach post-treating the indicator after their contact with the vaporous sterilant has been halted; however, the Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating, col.2, lines 61-64). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment aerating step after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64).

14. Claims 19-20 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) in view of Richard et al (U.S.P.N. 6,432,357) and further in view of Whitbourne et al (U.S.P.N. 3,992,154).

With respect to claims 19-20 and 38-39, both the Martens reference and the Menden reference fail to teach pre-treat or post-treat the indicators with same members. The Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating means) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and

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lines 31-44). The humidifying means is part of the chamber sterilization members. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator pretreatment means prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16).

With respect to claims 19-20 and 38-39, the Richard reference fails to teach post-treating indicators. The Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating means, col.2, lines 61-64). The aerating means is part of the chamber sterilization members. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment means after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64).

15. Claims 21 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martens et al (U.S.P.N. 5,482,684) in view of Richard et al (U.S.P.N. 6,432,357) and further in view of Whitbourne et al (U.S.P.N. 3,992,154) and Menden (U.S.P.N. 6,594,017).

With respect to claims 21 and 40, the Martens reference, the Richard reference and the Whitbourne reference all fail to teach the concept of using antechamber that includes pre-treatment and post-treatment means. The Menden reference discloses

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antechamber (figure 2, 5) and a movable member (figure 2, 3) and means for moving the movable member (figure 2, 10) back and forth between the chamber and the antechamber (figures 1-2, 5, 1 and 3). So, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor member that moves back and forth between the chamber and the antechamber for the sensor support means as taught by the Menden reference so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it.

Allowable Subject Matter

16. Claims 13-14, 27-28 and 44-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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